



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 16, 106, 110, 114, 117, 120, 123, 129, 179, and 211

[Docket No. FDA-2011-N-0920]

RIN 0910-AG36

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food; Extension of Comment Period for Information Collection Provisions

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period for information collection provisions.

SUMMARY: The Food and Drug Administration (FDA or “we”) is extending the comment period for the information collection related to the proposed rule on “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food” that appeared in the Federal Register of January 16, 2013. In the preamble to the proposed rule, FDA requested comments on the information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. We are taking this action in response to requests for an extension to allow interested persons additional time to submit comments on the information collection provisions associated with the rule.

DATES: The comment period for the proposed rule published January 16, 2013 (78 FR 3646), is extended. Submit either electronic or written comments by May 16, 2013.

ADDRESSES: To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory

Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the title “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.”

FOR FURTHER INFORMATION CONTACT:

Domini Bean,
Office of Information Management,
Food and Drug Administration,
1350 Picard Dr., PI50-400T,
Rockville, MD 20850,
Domini.Bean@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of January 16, 2013 (78 FR 3646), FDA published a proposed rule entitled “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food” with a 120-day comment period on the provisions of the proposed rule and a 30-day comment period on the information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). Comments on the provisions of the rule and on the information collection provisions will inform FDA's rulemaking to modernize the regulation for “Current Good Manufacturing Practice In Manufacturing, Packing, or Holding Human Food” and to add requirements for domestic and foreign facilities that are required to register under the Federal Food, Drug, and Cosmetic Act to establish and implement hazard analysis and risk-based preventive controls for human food.

OMB and FDA have received two requests for a 90-day extension of the comment period for the information collection provisions of the proposed rule. The requests conveyed concern that the current 30-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the information collection provisions submitted to OMB under the Paperwork Reduction Act of 1995.

We have considered the requests and are extending the comment period for the information collection for 90 days, until May 16, 2013. We believe that a 90-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues. A 90-day extension also will make the comment period for the information collection provisions the same as the comment period for the provisions of the proposed rule.

II. Request for Comments

Interested persons may either submit electronic comments regarding the information collection to oir_submission@omb.eop.gov or fax written comments to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285. All comments should be identified with the title "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food."

Dated: February 13, 2013.

Leslie Kux,

Assistant Commissioner for Policy.